K081269

MAR 2 0 2009

MEC Dynamics, Corp.
2225 Martin Ave., Suite I
Santa Clara, Ca 95050

SECTION 9
510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is K081269.

807.92 (a)(1): Name: MEC Dynamics Corporation

Address: 2225 Martin Avenue, Suite I
Santa Clara, CA 95050
Phone: 408-844-9279
FAX: 408 844-9285
Contact: Mr. Emmanuel Mpock

807.92 (a)(2): Device name- trade name and common name, and classification

Trade name: Avie™ A1C Test System

Common Name: Glycosylated hemoglobin assay

Classification: CFR §21.864.7470

807.92 (a)(3): Identification of the legally marketed predicate device

The Avie™ A1C Test System is substantially equivalent to other A1C test systems, and specifically, the G5 I/II HbA1C Test System (Provalis Diagnostics, Ltd.), most recently cleared under premarket notification K041635 on August 16, 2004.

807.92 (a)(4): Device Description

The Avie A1C test system is for the quantitative measurement of %A1C in fingerstick whole blood at the point-of-care (Professional or Physician Directed Home Use). The system consists of a small instrument ("Reader), a single-use diluent solution vial, single-use reagent test cartridges, and control levels I and II solutions.

To perform one test, the Reader is turned on by the push of a button on its top surface, and a self-check (optics and software) is performed automatically. If a

malfunction is detected, the Reader displays an error message on the LCD display. When the LCD display denotes "Ready" a test cartridge is inserted into an unambiguous slot in the reader. About four µL of whole blood is delivered into a vial containing wash solution or diluent, via a transfer pipette, and the vial is inverted five times for mixing. At the instruction of the reader (LCD read-out), three drops of blood mixture are applied to a well in the cartridge; the reactions then proceed automatically. There are no further procedural steps, and results in %A1C are displayed on the reader's LCD screen in approximately three minutes. The concentration of A1C is expressed as a percentage of the total hemoglobin as follows: %HBA1C = (HBA1C ÷ TOTAL HB) ×100

807.92 (a)(5): Intended Use

The Avie™ A1c test is a point of care system that quantitatively measures %A1C (glycated hemoglobin) in capillary whole blood samples. The test is for Professional and Physician Directed home use to monitor glycemic control in people with diabetes.

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807.92 (a)(6): Technological Similarities and Differences to the Predicate

Comparison between the Bayer A1C Now+™ the MEC Dynamics Avie™ A1C Systems

Characteristic	Bayer A1CNow+ K051321	MEC Dynamics Avie™ A1C K081269
Intended Use	Quantitative measurement of the percent of glycated hemoglobin	Quantitative measurement of the percent of glycated hemoglobin
Indications for Use	Used in the management and treatment of diabetes, for monitoring long-term glycemic control	Used in the management and treatment of diabetes, for monitoring long-term glycemic control
Risk to patient	Not a critical analyte – reflects glucose level over time	Not a critical analyte – reflects glucose level over time
Sample	Whole blood	Whole blood
Visual display	LCD readout	LCD readout
Hemolysate preparation	Manual via sample dilution kit	Manual, pipette and diluent supplied
Methodology	Immunoassay	Immunoassay
Detection method	Four-channel reflectance photometer	Transmission
Calibration	Factory calibrated	Factory calibrated
Recommended testing environment	Professional use	Prescription and Physician directed home use
Throughput	5 minutes per sample	3 minutes per sample
Reagent storage	Room temperature up to 120 days then refrigerate	Room temperature
Quality control requirements	External controls testing recommended: - With each new shipment - With each new lot - With each new operator - Whenever problems (storage, operator, instrument, or other) are identified - To ensure the storage conditions have not affected the product, run a control sample before running a patient sample if the test kit has been stored for more than a month and it has been a least a month since the last control testing.	External controls testing recommended: -Prior to home testing or at the start of each testing day. -Upon receipt of each new shipment or use of a new lot of cartridges -Whenever storage room conditions have been above 28°C (82°F). -To become familiar with the process or to perform training or retraining of testing personnel. -Whenever Avie™ A1c results do not match other clinical findings or symptoms.
Precision	Percent coefficient of variation within 5%	Percent coefficient of variation within 5%
Accuracy (estimated bias)	Versus NGSP Y= 1.02x- 0.23 R= 0.95 N=189	Versus NGSP Y=0.992± 0.001 R= 0.94 N=155
NGSP certification status	Certified	Certified

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807.92 (b)(1): Brief Description of Nonclinical Data

Studies were done that evaluated precision, linearity, interference, operational condition limits, and NGSP traceability for the Avie A1C Test System. The Avie A1C Test System demonstrates precision within 5 %CV at each of two levels-normal and abnormal %A1C. The Avie A1C Test System is linear between 5 and 14 %A1C. The Avie A1C Test System is insensitive to high physiological levels of triglyceride and bilirubin, high therapeutic levels of various over-the-counter pharmaceuticals, and hemoglobin levels ranging from approximately 9 g/dL to 20 g/dL. The system is sensitive to high levels of Metformin and glybenclamide (greater than 0.39 mg/dL and 0.02 mg/dL, respectively), as well as high levels of hemoglobinopathies. The Avie A1C Test System may be operated between temperatures of 18°C to 28°C. NGSP issued a certificate of traceability granting manufacturer certification to MEC Dynamics, Corporation.

807.92 (b)(2): Brief Description of Clinical Data

Clinical studies were conducted across four sites with approximately 150 subjects. Subjects first performed one Avie A1C test on themselves, and this was followed by a second Avie A1C test performed by a health care professional at the site. Venous blood was collected and sent to the NGSP laboratory in Columbia, MO. The regression statistics from this testing are described below.

Professional: Avie = 0.95 (NGSP) + 0.004 r = 0.94
Self: Avie = 0.99 (NGSP) + 0.001 r = 0.94

Clinical sensitivity testing of professional vs. self testing conducted at four sites with 109 subjects within the linearity range combined results were:

$Y=0.985+0.003$ $r=0.94$

The ability of untrained non-laboratory physician office staff was evaluated in an additional clinical sensitivity study conducted at three sites with 42 subjects. Testing comparing at least 2 untrained operators given only documented instructions and one trained operator per site resulted in the following combined values for trained vs. untrained operators:

$Y=1.05x -0.1899$ $r^{2=} 0.95$

807.92 (b)(3): Conclusions from Nonclinical and Clinical Testing

Nonclinical and clinical testing was performed for the Avie™ A1C Test System. The test system was shown to be safe and effective for its intended use.

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A comparison test of the Avie™ A1C Test System to the A1C Now+ was run at one site with 60 subjects with the following results:

$$Y=1.000x +0.004\ r^{2=}0.981 \text{ venous}$$
$$Y=0.993x +0.020\ r^{2=}0.946 \text{ capillary}$$

A comparison of venous to capillary samples using the Avie™ A1C Test System on 60 subjects results were:

$$Y=0.972x +0.191\ r^{2=}0.947$$

807.92 (b)(3): Conclusions from Nonclinical and Clinical Testing

Nonclinical and clinical testing was performed for the Avie™ A1C Test System. The test system was shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 2 0 2009

MEC Dynamics Corporation
c/o Mr. Emmanuel Mpock
2225 Martin Ave, Suite 1
Santa Clara, CA 95050

Re: k081269
Trade/Device Name: Avie A1C Test System
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Code: LCP
Dated: February 24, 2009
Received: February 25, 2009

Dear Mr. Mpock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indications for Use

510(K) Number (if known): K081269

Device Name: Avie™ A1C Test System

Indications for Use:

The Avie™ A1c test is a point of care system that quantitatively measures %A1C (glycated hemoglobin) in capillary or venous whole blood samples. The test is for prescription use and physician-directed home use to monitor glycemic control in people with diabetes mellitus. The device cannot be used in patients with hemoglobinopathies of HbF, HbC, and HbD.

Prescription Use __X__ **And/Or** Over the Counter Use ___
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety